REMARKS

Upon entry of the present amendment, claims 1, 6-7, 9-14, 17 and 20-33 will be pending in the application, with claims 20-29 having been withdrawn from examination by the Examiner. Support for the amendments to the claims is found throughout the application as filed. For example, the amendment to claim 1 is supported in original claims 6 and 9 and new claims 32 and 33 are supported at pages 4 and 51ff. Accordingly, the present amendments do not introduce new matter.

A. The Rejection of Claims Under 35 U.S.C. §112, First Paragraph, For Asserted Lack of Enablement Has Been Overcome

The Examiner rejected claims 1-14, 17-19 and 30 under § 112, first paragraph, for asserted lack of enablement. In supporting remarks, the Examiner asserted that the terms "steroid hormone" and "DNA-interacting molecule" encompassed a vast number of compounds and, with the exception of those specific compounds recited in the specification, one of skill would not be able to make the claimed compounds because the skilled artisan would not know what compounds were included in the definition of a "steroid hormone" or a "DNA-interacting molecule". In response, Applicants traverse.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of non-enablement for any of the rejected claims. Enablement is assessed from the perspective of one of ordinary skill in the art. Applicants disagree with the proposition that one of skill would not know what compounds were embraced by the claims.

The rejected claims are generally drawn to compounds comprising a steroid hormone linked to a DNA-interacting molecule. A "steroid hormone" is defined in the specification at page 4, paragraph 4, and elsewhere therein. Moreover, "steroid hormone" does have an ordinary and accustomed meaning in the art. Evidence thereof is provided in the form of a technical reference (Lehninger, Biochemistry (2d Ed.), Worth Publishers, Inc., 1979) from the relevant art, indicative of the state of the art at the relevant time. *See* Appendix A. This latter point is also consistent with the reasoning in *In re Herschler*, 591 F.2d 693, 697 (C.C.P.A. 1979) (a corticosteroid in DMSO was sufficient to support a biologically active steroid in DMSO because the use of known chemicals must be supported by a disclosure sufficient to lead one of skill to that class of compounds). The M.P.E.P. has adopted the reasoning in *Herschler*, *see* M.P.E.P. 2163(II(3)(a)(ii). Analogously, "DNA-interacting molecule" has been defined in the specification at, e.g., page 4, paragraph 5.

Applicants submit that this term is also sufficiently descriptive as to be self-defining and one of skill in the art would know that a "DNA-interacting molecule" is a molecule that interacts with DNA, e.g., by hybridization, intercalation, covalent crosslinking, ionic bonding, and the like, as recited in the specification (*see, e.g.*, page 4, paragraph 5). Applicants submit that in view of these facts, the instant claim rejection for asserted lack of enablement has been overcome and should be withdrawn. To expedite prosecution, however, Applicants have amended the claims (*see, e.g.*, claim 1) to recite specific steroid hormones linked to DNA-incorporating molecules. As amended, the claims are drawn to compounds, and methods for their preparation, that comprise any one of a set of specifically identified, and structurally well known, steroid hormones linked to DNA-incorporating molecules, a specific type of DNA-interacting molecule.

Applicants further submit that statements made by the Examiner in the outstanding office action confirm Applicants' position, as established above. In the remarks supporting the rejection in the office action, the Examiner asserted that a vast number of compounds are encompassed by the claims. The M.P.E.P. makes clear that claim scope cannot be equated with indefiniteness (M.P.E.P. § 2173.04) and, in this instance, the conclusion that any number of compounds, including a vast number, would be embraced by the claims confirms that the claims are definite.

For all of the foregoing reasons, Applicants submit that the rejection of claims 1-14, 17-19 and 30 under 35 U.S.C. § 112, first paragraph, for lack of enablement has been overcome and should be withdrawn. Additionally, a rejection of either of new claims 32 or 33 on analogous grounds would be improper for the reasons provided herein.

B. The Rejections of Claims Under 35 U.S.C. §112, Second Paragraph, For Asserted Indefiniteness Has Been Overcome

The Examiner rejected claims 1-14, 17-19, and 30 under 35 U.S.C. § 112, second paragraph, for asserted indefiniteness, supporting the rejection by again asserting that the claim terms "steroid hormone" and "DNA-interacting molecule" were unclear. As an asserted consequence, one of skill would not be able to determine the metes and bounds of the claimed invention. For reasons elaborated in section A and below, Applicants traverse.

In remarks supporting the lack of enablement rejection in the office action, the Examiner asserted that the terms "steroid hormone" and "DNA-interacting molecule", as used in the pending claims, defined a vast number of compounds. Regardless of the true scope of the pending claims, claim breadth is a concept that is distinct from claim indefiniteness. M.P.E.P. § 2173.04. Whether a claim embraces a relatively large, or small, number of compounds is not relevant to whether that claim is clear and definite. For this reason alone, Applicants submit that the Examiner has not established a *prima facie* case of indefiniteness under § 112, second paragraph.

Beyond the preceding dispositive remarks, Applicant submit that the term "steroid hormone" has a well-established meaning in the art, and the reference attached as Appendix A confirms that fact. One of skill in the art would understand what compounds were embraced by that term, and a set of those compounds is expressly recited in the presently amended claims. A "DNA-incorporating molecule," as noted above, has sufficient descriptive content to be self-defining. As defined in the instant specification, a "DNA-incorporating molecule" is a specific type of DNA-interacting molecule that becomes incorporated into DNA, such as by covalent bonding (e.g., crosslinking), ionic bonding, hydrogen bonding (e.g., hybridization), or by any other form of incorporation known in the art. The instant specification uses the term "DNA-incorporating molecule" in a consistent manner, disclosing that such molecules become incorporated into DNA and providing examples of such molecules (e.g., psoralen). Accordingly, neither "steroid hormone" nor "DNA-intcorporating molecule" is indefinite under § 112, second paragraph.

For the foregoing reasons, Applicants submit that the rejection of claims 1-14, 17-19, and 30 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been overcome and should be withdrawn. Further, a rejection of either of new claims 32 or 33 on analogous grounds would be improper for analogous reasons.

C. The Rejections of Claims Under 35 U.S.C. §102(b) Over Ponpipom *et al.* Have Been Overcome

The Examiner rejected claims 1-3, 5-8, 10-13, 17-19 and 30 under § 102(b) over Ponpipom *et al.*, asserting that the compounds and processes of making same that are disclosed by the reference are encompassed by the claims. In particular, the Examiner cited to page 1391, compound #23, as well as page 1392, col. 1, paragraph 1 and page 1394, col. 1, paragraph 5. In response, Applicants traverse.

Compound #23, disclosed at page 1391 of Ponpipom *et al.*, involves the direct attachment of dexamethasone to a glycopeptide via a carbamate bond. Ponpipom *et al.* discloses that the glycopeptide is a derivatized macrophage ligand at pages 1390-1391. The reference further states the need to demonstrate the uptake of the synthetic ligands into macrophages at page 1391. Thus, Ponpipom *et al.* discloses direct attachment of dexamethasone to a glycopeptide that results in interaction of the compound with a cell, not DNA. Nowhere in Ponpipom *et al.* is there a disclosure or suggestion that compound #23, or its constituent parts dexamethasone or the glycopeptide, is a DNA-interacting molecule such as a DNA-incorporating molecule. Moreover, the present claims (*see, e.g.*, claim 1) recite a spacer of 5-15 atoms and Ponpipom *et al.* discloses direct attachment of dexamethasone to a glycopeptide, neither disclosing nor suggesting any spacer. Further, the claims are drawn to urethane bonds for attachment of the spacer to each of the steroid hormone and the DNA-incorporating molecule. In contrast, Ponpipom *et al.* discloses attachment of dexamethasone to a glycopeptide via a carbonate bond. Thus, because Ponpipom *et al.* does not disclose or suggest (1) a DNA-interacting molecule such as a DNA-incorporating, (2) a spacer, or (3) attachment of the spacer via urethane bonds, Ponpipom *et al.* does not disclose each limitation of any of the pending claims. Accordingly, Ponpipom *et al.* does not anticipate any of the pending claims under 35 U.S.C. § 102(b).

For the foregoing reasons, Applicants submit that the rejection of claims 1-3, 5-8, 10-13, 17-19 and 30 under § 102(b) over Ponpipom *et al.* has been overcome and should be withdrawn. Additionally, a rejection of either of new claims 32 or 33 on analogous grounds would be improper for analogous reasons.

D. The Objection To Claims 15, 16 and 31 Has Been Rendered Moot

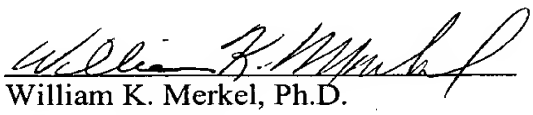
The Examiner objected to claims 15, 16 and 31 for depending from rejected base claims. In the present amendment, claims 15 and 16 have been canceled, thereby rendering moot the instant objection as applied to those claims. With respect to claim 31, Applicants note that this claim has been amended such that it now depends directly from claim 1. Additionally, the preceding amendments and remarks have established that claim 1 is now in condition for allowance. Accordingly, the objection to claim 31 for improperly depending from a rejected base claim has been overcome and may properly be withdrawn. Applicants further submit an objection to either of new claims 32 or 33 on analogous grounds would be improper.

IV. CONCLUSION

In view of the present amendment and supporting remarks, Applicants respectfully submit that claims 1, 6-7, 9-11, 14, 17 and 30-33 are in condition for allowance and request expedited notification thereof.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN

By 

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